

REMARKS

Claims 1 and 4-23 are pending in the present application.

The present invention provides, in part, a composition for percutaneous administration comprising:

(A) a mixture of polymers forming a surface-segregated film, said polymers consisting of (A-1) a hydrophobic polymer which has a surface tension of 10 to 45 mN/m, takes solid form at normal temperature and normal pressure, and is soluble or dispersible in water and/or a lower alcohol solution, and (A-2) a hydrophilic polymer which has a surface tension of 30 to 70 N/m;

(B) a hydrophilic active ingredient selected from the group consisting of plant extracts, animal extracts, guanidine derivatives, catecholamines, amino acids, vitamins, hormones and organic acids; and

(C) water and/or a lower alcohol (see Claim 1).

Applicants have found that such a composition exerts an excellent percutaneous absorption of the active ingredient, does not provide any adverse feelings, and is easy to use (see page 3, lines 1-6). Applicants submit that such a composition is neither disclosed, nor suggested by the art of record. Specifically, the disclosures of the cited references relate to a plastering preparation containing a drug ingredient and, therefore, are quite distinct from the present invention for the reasons set forth below.

The present invention relates to a composition for percutaneous administration comprising a mixture of polymers forming a surface-segregated film and a hydrophilic active ingredient, said polymers consisting of two different polymers having their surface tensions specified in the claims. Specifically, this composition takes advantage of a unique combination of two different polymers having their different surface tensions to form a

surface-segregated film, said combination (i.e., mixture) consisting of (A-1) a hydrophobic polymer which takes solid form at normal temperature and normal pressure, is soluble or dispersible in water and a lower alcohol solution, and has a silicone or fluorinated carbon chain, and (A-2) a hydrophilic polymer. As a result, percutaneous administration of an active ingredient can be effectively improved.

More specifically, once applied to the skin, the mixture of two polymers emerge as surface-segregated films divided into an outside layer which is formed of hydrophobic polymers and an inside layer close to the skin (hydrophilic polymer), which contains an active ingredient, thereby enabling said ingredient to smoothly penetrate into the skin.

In contrast, the art of record are all related to a plastering preparation comprising a carrier on which an active ingredient is applied. This is not the case in the composition of the present invention, which is not required to comprise such a carrier in that this composition itself is capable of forming films by use of the mixture of two different polymers (A-1) and (A-2), both of which have their specific surface tensions.

An example of the fundamental differences between the present invention and the art of record may be exemplified by referring to JP 60-123416. The preparation of JP 60-123416 comprises a water insoluble-polymer having adhesivity and a water-soluble polymer consisting of monomers having ethylene-unsaturated double bonds. This structure only tangentially relates to the composition of the present invention in terms of the combined use of a hydrophobic polymer and a hydrophilic polymer. Nonetheless, the composition of the present invention has many clear differences such that the composition of JP 60-123416 must be applied on a carrier, a hydrophobic polymer must be arranged on the side close to the skin, and this preparation must be adhesive at a normal temperature so it is a polymer with a minus value in terms of Tg. In contrast, the presently claimed composition comprises no such a

carrier in that the hydrophobic polymer can be automatically formed on the outer side and serves as a carrier by itself.

Moreover, Applicants wish to emphasize that the composition of the present invention contains no carrier and, when applied to the skin, is capable of forming a surface-segregated film.

In order to comply with the former requirements for response, Applicants offer the following specific comments regarding further distinctions between the claimed invention and the art of record.

The rejections of: (a) Claims 1-23 under 35 U.S.C. §102(b) over JP 60-123416; (b) Claims 1-23 under 35 U.S.C. §102(b) over JP 3-111530; (c) Claims 1-23 under 35 U.S.C. §102(b) over JP 2000-44476; (d) Claims 1-23 under 35 U.S.C. §102(b) over JP 62-240612; and (e) Claims 1-23 under 35 U.S.C. §102(b) over JP 05-112423, are traversed.

Applicants note that none of the aforementioned references disclose or suggest the specifically claimed *mixture* of polymers (A), much less the surface tension of the hydrophobic polymers and hydrophilic polymers contained in that mixture. Moreover, these references also fail to disclose or suggest admixing the polymer mixture of (A) with the claimed hydrophilic active ingredients (B) of present Claim 1.

In order for a reference to anticipate an invention, the reference “must teach every element of the claim” (MPEP §2131). Accordingly, JP 60-123416, JP 3-111530, JP 2000-44476, JP 62-240612, and JP 05-112423 do not anticipate the present invention.

Withdrawal of the anticipation rejections over JP 60-123416, JP 3-111530, JP 2000-44476, JP 62-240612, and JP 05-112423 is requested.

Finally, Applicants question the finality of the present Office Action as they have been robbed of the opportunity to objectively assess the Examiner's rejections over JP 60-123416, JP 3-111530, JP 2000-44476, JP 62-240612, and JP 05-112423 and timely respond to the same. In the previous Office Action, the Examiner rejected the originally pending claims by citing page and line number in each reference. Clearly, in order to justify such a citation, and ultimately the rejection, the Examiner must have had the opportunity to review these references and verify that the cited passages did in fact support such a rejection. However, Applicants were not provided with the translations of these references at the time the Office Action was issued.

Applicants undersigned Representative requested these translations during a discussion with Supervisory Examiner Kishore on April 23, 2003, who indicated that the Office would obtain English language translations of the 5 Japanese references upon which the Office based its rejections and that "the patentability of the claims will be determined based on these translations" (see paper number 8). Applicants then waited for more than two months (at additional cost to the Applicant for extensions of time) during which time the Office failed to provide the promised and required (see Ex parte Gavin, 62 USPQ2d 1680 (2001)) English translations.

Accordingly, Applicants responded to the first Office Action on the merits in which Applicants reminded the Office of its duty in accordance with Gavin. In addition, in the response filed on July 7, 2003, Applicants did *in fact* address the Japanese references.

First, Applicants noted that the English Abstracts clearly fail to anticipate the claimed invention noting that the English Abstracts fail to disclose or suggest the specifically claimed *mixture* of polymers (A), much less the surface tension of the hydrophobic polymers and hydrophilic polymers contained in that mixture. Applicants also noted that the English

Abstracts of the Japanese language references also fail to disclose or suggest the claimed hydrophilic active ingredients (B) of present Claim 1.

Second, with respect to the full disclosures, Applicants made the following statement: "Further, it is believed that the present amendment also obviates the rejections over the full disclosures; however, this will be further addressed once the Office complies with the requirements mandated by the Board in Gavin." (see response filed July 7, 2003, page 11, lines 22-24)

Despite the procedural breakdown in the previous Office Action, the Office has appeared to overlook Applicants response of July 7, 2003 and even the direction of Supervisory Examiner Kishore ("the patentability of the claims will be determined based on these translations"). In fact, the Office has elected to do no further examination on the merits, contrary to Supervisory Examiner Kishore's promise on the record, and instead has reissued the previous rejection over the Japanese language references. As such, the proceedings in this application have robbed Applicants of their opportunity for a prompt and full examination on the merits and in no way justifies the finality of the present Office Action.


Moreover, Applicants note that the claims have not been amended in the present Request for Reconsideration. In view of the foregoing and the lack of further amendment in response to the outstanding Office Action, any new grounds of rejection cannot be considered as being a result of any act on the behalf of Applicants. Therefore, it is earnestly solicited that any new Action be in a non-final Office Action.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

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